

Claims

1. A strain of Bifidobacterium isolated from resected and washed human gastrointestinal tract which is significantly immunomodulatory following oral consumption in humans.  
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2. A strain of Bifidobacterium as claimed in claim 1 which effects changes in an immunological marker when introduced into a system comprising cells which interact with the immune system and cells of the immune system.  
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3. A strain of Bifidobacterium as claimed in claim 2 wherein the cells which interact with the immune system are epithelial cells.
4. A strain of Bifidobacterium as claimed in claim 2 or 3 wherein the immunological marker is a cytokine.  
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5. A strain of Bifidobacterium as claimed in claim 4 wherein the cytokine is  $\text{TNF}\alpha$ .
6. A strain of Bifidobacterium as claimed in any of claims 2 to 5 wherein the cells which interact with the immune system and the immune system cells are of matched origin.  
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7. A strain of Bifidobacterium as claimed in any of claims 2 to 6 wherein the cells which interact with the immune system are of gastrointestinal, respiratory or genitourinary origin.  
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8. A strain of Bifidobacterium as claimed in any of claims 2 to 6 wherein the cells of the immune system are of gastrointestinal, respiratory or genitourinary origin.  
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9. A strain of *Bifidobacterium longum infantis* isolated from resected and washed human gastrointestinal tract which is significantly immunomodulatory following oral consumption in humans.
- 5 10. A strain of *Bifidobacterium* as claimed in any of claims 1 to 9 which has significant anti-inflammatory effect following oral consumption in humans.
- 10 11. A strain of *Bifidobacterium* isolated from resected and washed human gastrointestinal tract which is capable of combating the effects of inflammatory bowel disease, said capability being maintained in the presence of physiological concentrations of human bile and human gastric juice.
- 15 12. A strain of *Bifidobacterium longum infantis* according to claim 11, wherein the capability of combating the effects of inflammatory bowel disease is measured by measuring a reversal of a wasting disease induced in severe combined immunodeficient recipient mice (SCID) which have been administered purified CD4<sup>+</sup>, CD45RB<sup>high</sup> T cells.
- 20 13. A strain of *Bifidobacterium* as claimed in any preceding claim, which has inhibitory activity against a broad range of Gram positive and Gram negative bacteria.
- 25 14. A strain of *Bifidobacterium* as claimed in preceding claim, wherein the strain exhibits a broad-spectrum of activity against bacteria including *Staphylococcus*, *Pseudomonas*, *Coliform* and *Bacillus* species.
- 30 15. A strain of *Bifidobacterium longum infantis* UCC35624.
16. A strain of *Bifidobacterium longum infantis* UCC35624 or mutant or variant thereof isolated from resected and washed human gastrointestinal

tract which is significantly immunomodulatory following oral consumption in humans.

- 5 17. A strain of *Bifidobacterium longum infantis* UCC35624 as claimed in claim 16 wherein the mutant is a genetically modified mutant.
- 10 18. A strain of *Bifidobacterium longum infantis* UCC35624 as claimed in claim 16 wherein the variant is a naturally occurring variant of *Bifidobacterium longum infantis* UCC35624.
- 15 19. A strain of *Bifidobacterium* as claimed in any of claims 1 to 18 in the form of viable cells.
- 20 20. A strain of *Bifidobacterium* as claimed in any of claims 1 to 18 in the form of non-viable cells.
- 25 21. An antimicrobial agent obtained from a strain of *Bifidobacterium* as claimed in any of claims 1 to 20 which is antagonistic to the growth of other organisms.
- 20 22. A formulation which comprises a strain of *Bifidobacterium* as claimed in any of claims 1 to 20.
- 25 23. A formulation as claimed in claim 22, which comprises two or more strains of *Bifidobacterium*.
24. A formulation as claimed in claim 22 or 23, which includes another probiotic material.
- 30 25. A formulation as claimed in any of claims 22 to 24, which includes a prebiotic material.

26. A formulation as claimed in any of claims 22 to 25, which includes a strain of *Lactobacillus salivarius*.
27. A formulation as claimed in claim 26 wherein the strain of *Lactobacillus salivarius* is in the form of viable cells.
28. A formulation as claimed in claim 26 wherein the strain of *Lactobacillus salivarius* is in the form of non-viable cells.
29. A formulation as claimed in any of claims 26 to 28, wherein the *Lactobacillus salivarius* is isolated from resected and washed human gastrointestinal tract, the *Lactobacillus salivarius* being significantly immunomodulatory following oral consumption in humans.
30. A formulation as claimed in any of claims 26 to 29, wherein the strain of *Lactobacillus salivarius* is isolated from resected and washed human gastrointestinal tract which inhibits a broad range of Gram positive and Gram negative micro-organisms.
31. A formulation as claimed in any of claims 26 to 30 wherein the strain of *Lactobacillus salivarius* secretes a product having antimicrobial activity into a cell – free supernatant, said activity being produced only by growing cells and being destroyed by proteinase K and pronase E, the inhibitory properties of said strain and its secretory products being maintained in the presence of physiological concentration of human bile and human gastric juice.
32. A formulation as claimed in any of claims 26 to 31, wherein the strain of *Lactobacillus salivarius* is *Lactobacillus salivarius* strain UCC 118 or a mutant or variant thereof.

33. A formulation as claimed in claim 32 wherein the mutant is a genetically modified mutant.
- 5 34. A formulation as claimed in claim 32 wherein the variant is a naturally occurring variant of *Lactobacillus salivarius*.
35. A formulation as claimed in any of claims 22 to 34 which includes an ingestable carrier.
- 10 36. A formulation as claimed in claim 35 wherein the ingestable carrier is a pharmaceutically acceptable carrier such as a capsule, tablet or powder.
- 15 37. A formulation as claimed in claim 36 wherein the ingestable carrier is a food product such as acidified milk, yoghurt, frozen yoghurt, milk powder, milk concentrate, cheese spreads, dressings or beverages.
- 20 38. A formulation as claimed in any of claims 22 to 37 which further comprises a protein and/or peptide, in particular proteins and/or peptides that are rich in glutamine/glutamate, a lipid, a carbohydrate, a vitamin, mineral and/or trace element.
39. A formulation as claimed in claims 22 to 38 wherein the *Bifidobacterium* is present at more than  $10^6$  cfu per gram of delivery system.
- 25 40. A formulation as claimed in claims 22 to 39 which includes an adjuvant.
41. A formulation as claimed in claims 22 to 40 which includes a bacterial component.
- 30 42. A formulation as claimed in claims 22 to 41 which includes a drug entity.

43. A formulation as claimed in claims 22 to 42 which includes a biological compound.
44. A formulation as claimed in claims 22 to 43 for oral immunisation.
- 5 45. A strain of Bifidobacterium as claimed in any of claims 1 to 20 or a formulation as claimed in any of claims 22 to 44 for use in foodstuffs.
- 10 46. A strain of Bifidobacterium as claimed in any of claims 1 to 20 or a formulation as claimed in any of claims 22 to 44 for use as a medicament.
- 15 47. A strain of Bifidobacterium as claimed in any of claims 1 to 20 or a formulation as claimed in any of claims 22 to 44 for use in the prophylaxis and/or treatment of undesirable inflammatory activity.
- 20 48. A strain of Bifidobacterium as claimed in any of claims 1 to 20 or a formulation as claimed in any of claims 22 to 44 for use in the prophylaxis and/or treatment of undesirable gastrointestinal inflammatory activity such as inflammatory bowel disease eg. Crohns disease or ulcerative colitis, irritable bowel syndrome; pouchitis; or post infection colitis.
- 25 49. A strain of Bifidobacterium as claimed in any of claims 1 to 20 or a formulation as claimed in any of claims 22 to 44 for use in the prophylaxis and/or treatment of gastrointestinal cancer(s).
- 30 50. A strain of Bifidobacterium as claimed in any of claims 1 to 20 or a formulation as claimed in any of claims 22 to 44 for use in the prophylaxis and/or treatment of systemic disease such as rheumatoid arthritis.
51. A strain of Bifidobacterium as claimed in any of claims 1 to 20 or a formulation as claimed in any of claims 22 to 44 for use in the prophylaxis

and/or treatment of autoimmune disorders due to undesirable inflammatory activity.

5 52. A strain of Bifidobacterium as claimed in any of claims 1 to 20 or a formulation as claimed in any of claims 22 to 44 for use in the prophylaxis and/or treatment of cancer due to undesirable inflammatory activity.

10 53. A strain of Bifidobacterium as claimed in any of claims 1 to 20 or a formulation as claimed in any of claims 22 to 44 for use in the prophylaxis of cancer.

15 54. A strain of Bifidobacterium as claimed in any of claims 1 to 20 or a formulation as claimed in any of claims 22 to 44 for use in the prophylaxis and/or treatment of diarrhoeal disease due undesirable inflammatory activity, such as Clostridium difficile associated diarrhoea, Rotavirus associated diarrhoea or post infective diarrhoea.